



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2012-0159; FRL-9401-1]

Electronic Reporting; Toxic Substances Control Act Notifications of Substantial Risk and For Your Information Submissions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing that notifications of substantial risk under section 8(e) of the Toxic Substances Control Act (TSCA) and voluntary For Your Information (FYI) submissions may now be filed electronically using EPA's electronic document submission system, the Central Data Exchange (CDX). Use of this electronic reporting option will streamline and reduce the administrative costs and burdens of submitting paper-based notifications of substantial risks and FYI submissions.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

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For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, import, or distribute in commerce chemical substances and mixtures. The following North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. Potentially affected entities may include, but are not limited to:

- Petroleum refiners and distributors (NAICS code 324).
- Chemical manufacturers, processors, and distributors (NAICS code 325).
- Electronics manufacturing (NAICS codes 334 and 335).
- Paints and coatings and adhesive manufacturing (NAICS code 3255).
- Cleaning compounds and similar products manufacturing (NAICS code 3256).
- Automobiles manufacturing (NAICS code 3361).
- Manufacturers of plastic parts and components (NAICS code 325211).
- Aircraft manufacturing (NAICS code 336411).

If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2012-0159. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available

docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

II. Background

A. What Action is the Agency Taking?

The Agency is announcing the availability of an electronic reporting option for use by those who must submit a notification of substantial risk under TSCA section 8(e) and by those who wish to voluntarily submit a FYI submission. EPA is providing an electronic reporting option as part of broader Federal Government efforts to move to modern, electronic methods of information collection, which streamline processes and reduce overall burdens for all involved.

EPA's TSCA section 8(e) 1978 policy statement and the amended 2003 policy statement describe how paper-based submissions should be delivered to the Agency (Refs. 1 and 2). This document supplements the policy statements and describes how to use CDX, the Chemical Safety and Pesticide Program (CSPP) option, and the Chemical

Information Submission System (CISS) web-based reporting tool to submit the notifications of substantial risk required by TSCA section 8(e), as well as voluntary FYI submissions, electronically to the Agency. The Agency will make appropriate information about electronic reporting related to TSCA section 8(e) notification of substantial risk and FYI submissions available online at <http://www.epa.gov/oppt/tsca8e/pubs/reportingrequirements.html#submitreport>.

B. What is the Agency's Authority for Taking this Action?

TSCA section 8(e) states, “Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.” 15 U.S.C. 2607(e).

The Government Paperwork Elimination Act (GPEA), 44 U.S.C. 3504, (Ref. 3) requires Executive agencies to provide, when practicable, for:

1. The option of the electronic maintenance, submission, or disclosure of information as a substitute for paper.

2. The use and acceptance of electronic signatures.

C. Is Electronic Reporting through CDX Available for Other EPA TSCA Programs?

For previous documents discussing electronic reporting under TSCA, including the use of CDX, see Refs. 4-7.

D. What are the Benefits of CDX Reporting and Use of CISS?

EPA encourages submitters of TSCA section 8(e) notifications of substantial risk and voluntary submissions, including FYI submissions, to adopt electronic reporting as the preferred submission method. Electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency, as well as the cost to retain required records related to that submission. CISS, the web-based reporting tool, enables efficient data transmittal and reduces errors through the use of the built-in validation procedures. CISS also allows submitters to share a draft submission within their organization, and more easily save a copy for their records or future use. The resource and time requirements to review and process data by the Agency will also be reduced and document storage and retrieval will require fewer resources. EPA will also benefit from receiving electronic submissions and being able to communicate back electronically with submitters.

III. Electronic Reporting Procedures

This unit provides an overview of CDX, CSPP, and the CISS web-based reporting tool. It also provides instructions for the electronic reporting process for TSCA section 8(e) notifications of substantial risk and FYI submissions.

A. What is CDX?

CDX is EPA's point of entry for environmental data submissions to the Agency. CDX also provides the capability for submitters to access their data through the use of web services. CDX enables EPA to work with stakeholders, including governments, regulated industries, and the public to enable streamlined, electronic submission of data via the Internet. To report under the procedures discussed in this notice, submitters would

register with CDX, select the CSPP option, and use CISS to access reporting of TSCA section 8(e) notification of substantial risk and FYI submissions. More information about CDX is available online at <http://www.epa.gov/cdx>.

B. What is CISS?

CISS is a web-based reporting tool for the submission of forms, reports, and other documents including TSCA section 8(e) notification of substantial risk and FYI submissions, electronically to the Agency. The tool is available for use with Windows, Mac, Linux, and UNIX computer systems, using “Extensible Markup Language” (XML) specifications for efficient data transmission across the Internet. CISS provides user-friendly navigation, works with CDX to secure online communication, creates a completed Portable Document Format (PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments, or by other electronic standards, such as XML. As currently implemented, one or more representatives from each facility must establish an account with EPA’s CDX in order to prepare, transmit, certify, and submit forms, reports, and other documents.

C. How Will TSCA Section 8(e) Notification of Substantial Risk and FYI Submissions be Submitted via the Internet Using CDX?

Submitters register with EPA’s CDX, select the CSPP Program, and use CISS to prepare a data file for submission.

1. *Registering with CDX.* To submit electronically to EPA via CDX, a user would register with CDX available online at <https://cdx.epa.gov>. CDX registration enables EPA to authenticate user identities and verify user authorizations.

To register in CDX, the CDX registrant (also referred to as “Electronic Signature Holder” or “Public/Private Key Holder”) would agree to the terms and conditions,

provide information about the user and organization, select a user name and password, and follow the procedures outlined in the guidance document for CDX available online at http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf.

2. *Submission.* Submitters choosing to submit electronically will use CISS to prepare their submissions. CISS guides users through a “hands-on” process of creating an electronic submission. Once a user completes the relevant data fields and attaches appropriate PDF files or other file types, such as XML files, the web-based tool validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. Further instructions on submitting information and instructions for uploading PDF attachments or other file types, such as XML will be available through CISS reporting guidance available online at <http://www.epa.gov/oppt/tsca8e/pubs/reportingrequirements.html#submitreport>.

D. Can CBI be Submitted Using CISS?

Yes, CISS enables the user to submit CBI in an electronic format. All information sent by the user via CDX is transmitted securely to protect CBI. CISS also guides the user through the process of submitting CBI by prompting the user to check a CBI checkbox if using a form or by submitting a scanned document containing CBI by bracketing, underlining, or otherwise marking the confidential information on the document prior to scanning. As with paper-based submissions, a sanitized copy of any document containing CBI would be included by the user in the electronic submission. The CISS reporting guidance instructs users on how to submit CBI and substantiate CBI claims information using CISS.

E. How Will CBI be Protected When Submitting via CDX?

The Agency ensures secure transmission of the data, reports, and other documents sent from the user through the Internet via the Transport Layer Security (TLS) 1.0 protocol. TLS 1.0 is a widely used approach for securing Internet transactions and is endorsed by the National Institute of Standards and Technology (NIST) as a means for protecting data sent over the Internet. See NIST Special Publication 800-52, “Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations,” available online at <http://csrc.nist.gov/publications/nistpubs/800-52/SP800-52.pdf>.

In addition, CISS enables the submitter to electronically sign, encrypt, and transmit submissions, which the Agency subsequently provides back to the user as an unaltered copy of record. This assures the user that the Agency has received exactly what the user sent to the Agency. CISS encrypts using a module based on the 256-bit Advanced Encryption Standard (AES) adopted by NIST. Details about AES can be found on the NIST website at <http://csrc.nist.gov/publications/fips/fips197/fips-197.pdf>. EPA may incorporate other encryption modules into future versions of CISS. Information submitted via CDX is processed within EPA by secure systems certified for compliance with Federal Information Processing Standards available online at <http://www.nist.gov/itl/fips.cfm>.

IV. References

The following is a list of references that are specifically referenced in this document and placed in the docket that was established under docket ID number EPA-HQ-OPPT-2012-0159.

1. EPA. Toxic Substance Control Act; Notification of Substantial Risk Under Section 8(e); Notice. **Federal Register** (43 FR 11110, March 16, 1978) (FRL-849-2).
2. EPA. TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance; Notice. **Federal Register** (68 FR 33129, June 3, 2003) (FRL-7287-4).
3. EPA. Cross-Media Electronic Reporting; Final Rule. **Federal Register** (70 FR 59848, October 13, 2005) (FRL-7977-1).
4. EPA. TSCA Inventory Update Reporting Rule; Electronic Reporting, Direct final rule. **Federal Register** (71 FR 52494, September 6, 2006) (FRL-7752-8).
5. EPA. TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations; Final rule. **Federal Register** (75 FR 773, January 6, 2010) (FRL-8794-5).
6. EPA. TSCA Inventory Update Reporting Modifications; Chemical Data Reporting; Final rule. **Federal Register** (76 FR 50816, August 16, 2011) (FRL-8872-9).
7. EPA. Electronic Reporting Under the Toxic Substances Control Act; Proposed rule. **Federal Register** (77 FR 22707, April 17, 2012) (FRL-9337-5).

V. Statutory and Executive Order Reviews

This action is not a regulation, nor does it impose any binding requirements. Submitters of TSCA section 8(e) notifications of substantial risk are not required to adopt the electronic reporting option described in this document in order to satisfy the statutory requirements. In addition, this action does not require anyone seeking to voluntarily submit information, including FYI submissions, to do so using an electronic reporting method.

A. Executive Order 12866 and Executive Order 13563

This action is not a “regulatory action” as that term is defined in Executive Order 12866 entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Therefore, it is not subject to review by under Executive Orders 12866 and 13563 entitled “Improving Regulation and Regulatory Review” (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, an collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control numbers for EPA's regulations, after appearing in the **Federal Register**, are listed in 40 CFR part 9 and 48 CFR chapter 15, and included on the related collection instrument or form, if applicable.

The information collection activities related to TSCA section 8(e) and FYI submissions, including the CDX registration activities associated with the electronic reporting option, have been approved by OMB under OMB control number 2070-0046 (EPA ICR No. 0794.13). The estimated burden of initial section 8(e) or FYI submissions is 51 hours per response when submitted in paper and 49 hours per response when submitted electronically. The estimated burden of follow-up/supplemental section 8(e) or FYI submissions is 5 hours per response when submitted in paper and 4 hours per response when submitted electronically. The total annual burden approved by OMB is 18,518 hours. Burden is defined in 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

Since this action is not a rule under the Administrative Procedure Act (5 U.S.C. 551(4)), and does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

D. Unfunded Mandates Reform Act and Executive Orders 13132 and 13175

This action will not have substantial direct effects on State or tribal governments, on the relationship between the Federal Government and States or Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and States or Indian Tribes. As a result, no action is required under Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), or under Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). Nor does it impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531-1538).

E. Executive Orders 13045, 13211, and 12898

As indicated previously, this action is not a “regulatory action” as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997) and Executive Order 13211 entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). In addition, this action also does not require any special considerations under Executive Order 12898 entitled “Federal Actions to Address

Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

F. National Technology Transfer and Advancement Act

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (15 U.S.C. 272 note).

VI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq. does not apply because this action is not a rule as that term is defined in 5 U.S.C. 804(3).

List of Subjects

Environmental protection, Administrative practice and procedure, Business and industry, Chemicals, Reporting and recordkeeping requirements.

Dated: March 12, 2014.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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